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- An isolated antigen or fragment thereof which is immunologically accessible on greater than 50% of known strains of Neisseria meningitidis.
- The isolated antigen or fragment of claim 1 which is immunologically accessible on about 99% of known strains of Neisseria meningitidis.
- The isolated antigen or fragment of claim 1 in which immunological accessibility is determined by using an agglutination assay, an ELISA, a RIA, an immunoblotting assay, a dot-enzyme assay, a surface 15 accessibility assay, or a combination of these assays.
 - The isolated antigen of fragment of claim 1 which is a protein.
- 20 The protein of claim 4 which has a molecular weight of 5. about 22 kilodaltons.
 - The protein of claim 4 which has a molecular weight of about 18 kilodaltons.

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- The protein of claim 5 which has the amino acid sequence selected from the sequences of: Figure 1 (SEQ ID NO:2), Figure 8 (SEQ ID NO:4), Figure 9 (SEQ ID NO:6), and Figure 10 (SEQ ID NO:8).
- The protein of claim 5 which has the amino acid sequence of Figure 1 (SEQ ID NO:2).
- The protein of claim 5 in substantially pure form.

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- 10. The protein of claim 9, wherein said susbtantially pure form is obtained by the steps of:
 - a) isolating a culture of Neisseria meningitidis bacteria,
 - b) isolating an outer membrane portion from the culture of the bacteria; and
 - c) isolating said antigen from the outer membrane portion.
- 11. The protein of claim 10, wherein step (c) includes the additional step of treating the outer membrane portion with proteinase K followed by protein fractionation.
- 15 12. A DNA sequence encoding at least a portion of at least one antigen of the Neisseria meningitidis 22 kDa surface protein, said sequence being selected from the group consisting of:
 - a) the DNA sequence of Figure 1 (SEQ ID NO:1);
- 20 b) the DNA sequence of Figure 8 (SEQ ID NO:3);
 - c) the DNA sequence of Figure 9 (SEQ ID NO:5);
 - d) the DNA sequence of Figure 10 (SEQ ID NO:7);
 - e) analogues or derivatives of the foregoing DNA sequences;
- 25 f) DNA sequences degenerate to any of the foregoing DNA sequences; and
 - g) fragments of any of the foregoing DNA sequences; wherein said sequences encode a product that displays the immunological activity of the Neisseria meningitidis 22 kDa surface protein.
 - 13. A DNA sequence encoding at least a portion of at least one antigen of the Neisseria meningitidis 22 kDa

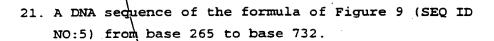




surface protein, said sequence being selected from the group consisting of:

- a) the DNA sequence of Figure 1 (SEQ ID NO:1);
- b) analogues or derivatives of the foregoing DNA sequence
- c) DNA sequences degenerate to any of the foregoing DNA sequences; and
- d) fragments of any of the foregoing DNA sequences; wherein said sequences encode a product that displays the immunological activity of the Neisseria meningitidis 22 kDa surface protein.
- 14. A DNA sequence according to claim 12, wherein said analog is selected from the DNA of Neisseria

 gonorrhoeae.
 - 15. A DNA sequence according to claim 12, wherein said analog is selected from the DNA of Neisseria lactamica.
 - 16. A DNA sequence of the formula of Figure 1 (SEQ ID NO:1) from base 143 to base 667.
- 17. A DNA sequence of the formula of Figure 1 (SEQ ID NO:1) from base 200 to base 667.
 - 18. A DNA sequence of the formula of Figure 8 (SEQ ID NO:3) from base 116 to base 643.
- 30 19. A DNA sequence of the formula of Figure 8 (SEQ ID NO:3) from base 173 to base 643.
 - 20. A DNA sequence of the formula of Figure 9 (SEQ ID NO:5) from base 208 to base 732.



- 5 22. A DNA sequence of the formula of Figure 10 (SEQ ID NO:7) from base 241 to base 765.
 - 23. A DNA sequence of the formula of Figure 10 (SEQ ID NO:7) from base 298 to base 765.
- 24) A fragment of a DNA sequence according to claim 13, wherein said fragment is selected from the group consisting of: one of the peptides illustrated in Figure 15 (SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, and SEQ ID NO:26).
 - 25.) A fragment of a DNA sequence comprising from amino acid 31 to amino acid 55 of Figure 1 (SEQ ID NO:1).
- 26. A fragment of a DNA sequence comprising from amino acid 51 to amino acid 86 of Figure 1 (SEQ ID NO:1).
 - 27. A fragment of a DNA sequence comprising from amino acid 110 to amino acid 140 of Figure 1 (SEQ ID NO:1).
- 30 28. A recombinant DNA molecule comprising a DNA sequence selected from the group consisting of the DNA sequences of claims 13, 16, or 17, and one or more expression control sequences operatively linked to the DNA sequence.

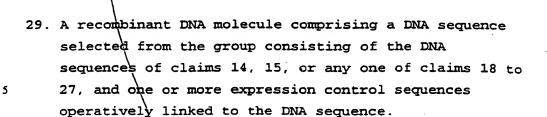
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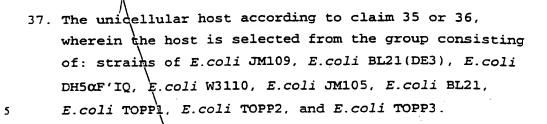




- 30. The recombinant DNA molecule of claim 28, wherein said expression control sequence is an inducible expression vector.
- 31. The recombinant DNA molecule of claim 29, wherein said expression control sequence is an inducible expression vector.
- 32. The recombinant DNA molecule of claim 30 or 31, wherein said vector is induced by stimuli selected from: temperature, presence of lactose, and presence of IPTG.
 - 33. The recombinant DNA molecule of claim 32, wherein said vector is selected from: λ PL, λ PR, TAC, T7, T3, LAC, and TRP promoters.
- 25 (34.) A plasmid selected from the group consisting of: pNP2202, pNP2203, and pNP2204
 - 35. A unicellular host transformed with a recombinant DNA molecule of claim 28.
 - 36. A unicellular host transformed with a recombinant DNA molecule of claim 29.

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- 38. The unicellular host according to claim 35 or 36, wherein the host is selected from the group consisting of strains of E.coli JM109 and E.coli BL21(DE3).
- 39. A Neisseria meningitidis 22kDa surface protein in substantially pure form obtained by the culturing of a unicellular host according to claim 35 or 36 and isolating said protein.
 - 40. A polypeptide coded for by a DNA sequence of any one of claims 13, 16 and 17,
- 41. A polypeptide coded for by a DNA sequence of any one of claims 14, 15 and 18 to 27.
 - 42. A method for producing a DNA sequence comprising the steps of culturing the unicellular host of claim 35 or 36 and isolating said DNA sequence.
 - 43. A method for producing a polypeptide comprising the steps of culturing the unicellular host of claim 35 or 36 and isolating said polypeptide.
- 30 44. A polypeptide in substantially pure form as obtained by the method of claim 43.



- 45. A method for isolating the antigen of claim 1 comprising:
 - a) isolating a culture of Neisseria meningitidis bacteria,
- b) isolating an outer membrane portion from the culture of the bacteria; and
 - c) isolating said antigen from the outer membrane portion.
- 10 46. The method of claim 45, wherein step (c) includes the additional steps of treating the outer membrane portion with proteinase K followed by protein fractionation.
- 15 47. A pharmaceutical composition comprising one or more antigens or fragments thereof according to any one of claims 1 to 5, 8, 13, 16, and 17.
- 48. A pharmaceutical composition comprising one or more antigens or fragments thereof according to claim 40.
 - 49. A pharmaceutical composition comprising one or more antigens or fragments thereof according to claim 41.
- 25 50. A pharmaceutical composition comprising one or more antigens or fragments thereof according to any one of claims 6, 7, 9, 12, 14, 15, and 18 to 27.
- 51. The pharmaceutical composition of claim 49, which is a vaccine.
 - 52. The pharmaceutical composition of claim 50, which is a vaccine.

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- 53. The pharmaceutical composition of claim 49, further comprising one or more pharmaceutically acceptable excipients.
- 5 54. The pharmaceutical composition of claim 50, further comprising one or more pharmaceutically acceptable excipients.
- 55. A method for preventing infection of a patient by

 Neisseria meningitidis comprising the administration

 of a pharmaceutically effective amount of the vaccine

 of claim 51 or 52
- 56. The use of a pharmaceutically effective amount of the

 Neisseria meningitidis 22kDa surface protein or a

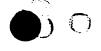
 fragment, analogue, or derivative thereof for the

 prevention of Neisseria meningitidis infection in
 humans.
- 20 57. The use of a pharmaceutically effective amount of the Neisseria meningitidis 22kDa surface protein or a fragment, analogue, or derivative thereof for the prevention of Neisseria gonorrhoeae infection in humans.
 - 58. The use of the Neisseria meningitidis 22 kDa surface protein or a fragment, analogue, or derivative thereof for the manufacture of a vaccine for the prevention of Neisseria meningitidis infection in humans.
 - 59. The use of the Neisseria meningitidis 22 kDa surface protein or a fragment, analogue, or derivative thereof for the manufacture of a vaccine for the prevention of Neisseria gonorrhoeae infection in humans.

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- 60. An antibody or fragment thereof that specifically binds to a protein with a molecular weight of approximately 22 kilodaltons present on greater than 50% of known strains of Neisseria meningitidis.
- 61. The antibody or fragment of claim 60 that specifically binds to about 99% of known strains of Neisseria meningitidis.
- 62. The antibody or fragment of claim 60 which is a monoclonal antibody or fragment thereof.
- 63. The monoclonal antibody or fragment of claim 62 which is of murine origin.
 - 64. The monoclonal antibody or fragment of claim 63 which is of an IgG isotype.
- 20 (65) The monoclonal antibody or fragment of claim 62 which is Me-1, Me-2, Me-3, Me-5, Me-6, or Me-7.
 - 66. The monoclonal antibody of claim 62 which is the monoclonal antibody Me-1 or Me-7.
 - 67. A method for isolating the antibody of claim 60 comprising:
 - a) introducing a preparation of Neisseria meningitidis into a mammal; and
- 30 b) isolating serum from the mammal containing said antibody.
 - 68. A method for isolating the monoclonal antibody of claim 62 comprising:

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- a) introducing a preparation of Neisseria meningitidis to antibody producing cells of a mammal;
- b) fusing the antibody producing cells with myeloma cells to form hybridoma cells; and
- 5 c) isolating said monoclonal antibody from the hybridoms cells.
- 69. A pharmaceutical composition comprising one or more antibodies or fragments thereof according to any one of claims 60-66.
 - 70. The pharmaceutical composition of claim 69 which is a vaccine.
- 15 71 The pharmaceutical composition of claim 69, further comprising a pharmaceutically acceptable excipient.
 - 72.) The pharmaceutical composition of claim 69, wherein the antibody is Me-1 or Me-7.
 - 73. A method for treating a patient infected with or suspected of being infected with Neisseria meningitidis comprising the administration of a pharmaceutically effective amount of the vaccine of claim 70.
 - 74. A method for the detection of Neisseria meningitidis antigen in a biological sample containing or suspected of containing Neisseria meningitidis antigen comprising:
- a) isolating the biological sample from a patient;
 - b) incubating the antibody or fragment of claim 60 with the biological sample to form a mixture; and

- c) detecting specifically bound antibody or bound fragment in the mixture which indicates the presence of Neisseria meningitidis antigen.
- 5 (75.) The method of claim 72 wherein the antibody is Me-1 or Me-7.
 - 76. A method for the detection of antibody specific to

 Neisseria meningitidis antigen in a biological sample

 containing or suspected of containing said antibody

 comprising:
 - a) isolating the biological sample from a patient;
 - b) incubating the antigen or fragment of claim 1 with the biological sample to form a mixture; and
- 15 c) detecting specifically bound antigen or bound fragment in the mixture which indicates the presence of antibody specific to Neisseria meningitidis antigen.
- 20 77. The method of claim 76 wherein the antigen is the Neisseria meningitidis 22 kDa surface protein.
 - 78. A method for the detection of pathogenic Neisseria bacteria in a biological sample containing or suspected of containing such bacteria comprising:
 - a) isolating the biological sample from a patient;
 - b) incubating a DNA probe having the DNA sequence of claim 13 with the biological sample to form a mixture; and
- 30 c) detecting specifically bound DNA probe in the mixture which indicates the presence of Neisseria bacteria.

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- 79. A method for the detection of pathogenic Neisseria bacteria in a biological sample containing or suspected of containing such bacteria comprising:
 - a) isolating\the biological sample from a patient;
 - b) incubating a DNA probe having the DNA sequence of claim 12 with the biological sample to form a mixture; and
 - c) detecting specifically bound DNA probe in the mixture which indicates the presence of Neisseria bacteria.
- 80.) The method of claim 78 wherein the DNA probe has the 525 base pair sequence of Figure 1 (SEO ID NO:1).
- 15 (81) The method of claim 7/8 wherein the DNA probe has a portion of the 525 base pair sequence of Figure 1 (SEQ ID NO:1).
- 82. The method of claim 79 wherein the DNA probe has the full or a portion of the 528 base pair sequence of 20 Figure 8 (SEQ ID NO:3).
- 83. The method of claim 79 wherein the DNA probe has the full or a portion of the 525 base pair sequence of 25 Figure 9 (SEQ ID NO:5).
 - 84. The method of claim 79 wherein the DNA probe has the a portion or the full 525 base pair sequence of Figure 10 (SEQ ID NO:7).
 - The method of claim 78 wherein the DNA probe is an oligomer having a sequence complementary to at least about 6 contiguous nucleotides of the Neisseria

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meningitidis 2 kDa surface protein of Figure 1 (SEQ ID NO:1).

- 86. The method of claim 79 wherein the DNA probe is an oligomer having a sequence complementary to at least about 6 contiguous nucleotides of the Neisseria meningitidis 22 kDa surface protein of sequences selected from: Figure 8 (SEQ ID NO:3), Figure 9 (SEQ ID NO:5), and Figure 10 (SEQ ID NO:7).
 - 87. The method of claim 85 or 86 which further comprises:

 a) providing a set of oligomers which are primers for a polymerase chain reaction method and which flank the target region; and
- b) amplifying the target region via the polymerase chain reaction method
 - 88. A method for the detection of Neisseria meningitidis in a patient comprising:
- a) labeling the antibody or fragment of claim 60 with a detectable label;
 - b) administering the labeled \(\frac{\text{antibody}}{\text{or}} \) or labeled fragment to the patient; and
- c) detecting specifically bound labeled antibody or labeled fragment in the patient which indicates the presence of Neisseria meningitidis.
- 89. The use of a pharmaceutically effective amount of an antibody specific to the Neisseria meningitidis 22 kDa surface protein for the prevention of Neisseria meningitidis infection in humans.
 - 90. The use of the Neisseria meningitidis 22 kDa surface protein or a fragment, analogue, or derivative thereof

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